REMARKS

Applicants wish to thank the Examiner for the review of the present application. Applicants have amended claims 1, 10, 128-130, 144-146, 153, 190 and 230. Claims 127 and 143 have been cancelled. Claims 1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86 and 94-126, 128-142, 144-153, 190 and 228-256 are now pending in the application. No new matter has been added.

Claim Objections

Claims 127-131 and 143-147 stand objected to for certain claim informalities, namely referring to "a three-dimensional model" in dependent claims where the term has been incorporated into the referenced independent claims. Claims 127 and 143 have been cancelled. Claims 128-130 and 144-146 have been amended to depend directly from independent claims 10 and 1. Accordingly, Applicants believe this objection has been resolved.

35 U.S.C. § 103

Claims 1, 7, 10, 15, 153 and 190 stand rejected under 35 U.S.C §103(a) as being unpatentable over Ateshian et al. (US 6,126,690) (Ateshian) in view of Aouni-Ateshian et al. (US 6,161,080) (Aouni-Ateshian). Claims 18-19, 21, 55-58, 60, 66-71, 85-86, 94-152 and 228-256 are further rejected in view of Delp et al. (US 5,682,886) (Delp) and Paul et al. (US 5,320,102) (Paul). Claims 20 and 59 are further rejected in view of George, III et al. (US 6,175,655) (George). Claims 22 and 61 are further rejected in view of Goldberg et al. (US 6,835,377) (Goldberg).

Amended claim 1 of the present application is directed to a method of creating an implant for treating joint disease by obtaining from image data a damaged or diseased joint information about the three-dimensional geometry of the joint, including normal and/or diseased articular cartilage and subchondral bone; creating a three-dimensional electronic model of at least a portion of the joint including normal and/or diseased articular cartilage and subchondral bone, wherein the model includes a geometry of at least a portion of an articular surface of the joint; and creating an implant based on the three-dimensional model, wherein at least a portion of said implant has an outer articular surface derived from the geometry of at least a portion of the articular surface of

the joint.

Ateshian does not disclose such a method, even when combined with Aouni-Ateshian. Neither reference discloses deriving an implant having an articular surface portion that is derived from a three-dimensional model of a diseased or damaged joint, wherein at least of portion of an outer articular surface is derived from the geometry of at least a portion of the articular surface of the joint.

Ateshian discloses joint prostheses derived from proxies for diseased bone: either using a database of "archetypes" or using a "contralateral joint." Ateshian does not disclose deriving an implant from the articular surface of the diseased joint itself. Although the Office Action notes that "Ateshian show[s] obtaining image data of the surface of a joint, modifying the image data to provide a more functional surface topography, and the[n] fabricating a joint prosthesis" (Office Action at 3), this is not done using the diseased or damaged joint. Instead, it is done using image data of a contralateral joint. This is explicitly disclosed in the detailed description of the invention. Ateshian states that the method for "modifying the image data" involves comparing a joint needing replacement with a healthy contralateral joint of the patient. (See col. 9, lines 21-40 and 56-61.) The only method disclosed by Ateshian that involves using data from a diseased joint also involves a comparison to a database of archetypes as discussed above. None of the methods that Ateshian discloses derive an outer articular surface portion of an implant from the geometry of the articular surface of a diseased or damaged joint.

Aouni-Ateshian also does not disclose such a method. Aouni-Ateshian discloses a "three dimensional software model of anatomical joints, which predict the quasi-static kinematic orientation and position of any number of movable bodies, as well as predicting contact forces, contact areas and ligament forces." (Aouni-Ateshian, Col. 5, lines 1-6.) Aouni-Ateshian is focused on the development of models of anatomical joints, and does not disclose the creation of implants in any detail. With regard to designing prostheses, Aouni-Ateshian discloses only that "[p]rostheses and other medical instruments may be more efficiently designed and evaluated using a model." (See col. 1, lines 62-64.) Aouni-Ateshian fails to disclose any detail about the structure of such prostheses.

Furthermore, not only does Aouni-Ateshian not disclose a patient-specific implant per se, it fails even to disclose that a "patient-specific" model of a damaged or diseased joint could be derived directly from image data of a diseased or damaged joint. Aouni-Ateshian discloses only that it "may be possible" to create such patient-specific models in the future, due to "improving" non-invasive in-vivo imaging. Although, as the Examiner notes, Aouni-Ateshian does state that "several investigators have reconstructed cartilage topography and thickness from MR images", Aouni-Ateshian makes clear that such reconstructions are different than the three-dimensional models of the invention. There is simply no disclosure in Aouni-Ateshian that indicates that, as of the filing of the application, the inventors could create a three-dimensional patient-specific model directly from a diseased or damaged joint, much less derive an articular implant surface from such a model.

The office action then further adds several additional references to fill in additional elements not found in Ateshian and Aouni-Ateshian. None of those references – either alone or in combination – discloses creating a patient-specific implant having an outer articular surface derived from a three-dimensional model of the damaged or diseased joint, as required in the independent claims as amended. In claim 1, the outer articular surface is created based on information concerning cartilage or subchondral bone that is obtained from the image data. In claim 10, the outer articular surface is created based on information concerning cartilage that is obtained from the image data. In claims 153 and 190, the outer articular surfaces are formed or created based on information about the underlying subchondral bone of the joint.

None of the art cited by the Examiner discloses these features of the claims. Delp, for example, primarily discloses a surgical planning system that can be used with existing implants to plan surgeries or assist in robotic surgeries. Delp, however, does not disclose a system that can be used to create implants or physical models based on the image data that is used. In fact, Delp explicitly states that the implants used in conjunction with the surgical planning methods are those that are commercially available, and further states that the structure of these implants are not important.

> It is intended that the invention can be used with any commercially-available prosthesis, whether standard or custom-designed, and ***the structure of the***

> ***prosthesis is not important*** except that data representing its size and configuration must be loaded into the planning software in order to provide accurate sizing and placement information and useful planning information.

(See Delp, col. 12, lines 47-61 (emphasis added).) Thus, not only does Delp not disclose the methods of forming and creating implants and physical models as claimed, Delp actually teaches away from such concepts by explicitly stating that the structure of such devices are not important.

Goldberg also fails to disclose the methods as claimed and, instead, discloses very different technology. Goldberg is directed to the regeneration of cartilage using, for example, "a suspension of purified fibrillar collagen or modified collagen and culture-expanded human mesenchymal stem cells (hMSCs)." (Goldberg Col. 5, lines 48-50.) Goldberg states in the abstract that the invention is "[f]or repair of cartilage damaged as part of the degenerative effects of osteoarthritis" and that "the inventors have found that the human mesenchymal stem cell approach makes it possible to [among other things] regenerate both shallow cartilage chondral defects and full thickness cartilage defects…" Goldberg does not disclose implants or physical models as claimed. Thus, nothing in Goldberg would cause one skilled in the art to combine the references with any other references to obtain the claimed inventions.

Paul similarly fails to disclose all of the claimed elements of the independent claims. As noted in the abstract, Paul uses MRI images to diagnose proteoglycan deficiency in articular cartilage. Paul does not disclose any implants or physical models, as those concepts are absent from the specification. More specifically, Paul does not teach or suggest all of the elements of the claims as amended, and nothing in Paul would cause one skilled in the art to combine that reference with others to create the claimed methods.

Finally, as with the other cited art, George, III does not teach or suggest the claimed methods, and nothing in that reference would cause one skilled in the art to combine that reference with others to create the claimed methods. George, III discloses methods of generating and manipulating three-dimensional images from MRIs and other medical images, but does not disclose the creation for formation of implants and physical models using those images. Thus, George does not teach or suggest the independent claims as amended.

Claims 7, 15, 18-22, 55-61, 66-71, 85-86, 94-126, 128-142 and 144-152, which depend from claims 1 and 10, and claims 228-256, which depend from claims 1, 153 and 190, are each patentable for at least the same reasons. Thus, all of the pending claims in the application are patentable over each and every combination of Ateshian, Delp, Aouni-Ateshian, Goldberg, Paul, and George, III.

CONCLUSION

All pending claims are believed to be in a form suitable for allowance. Therefore, the application is believed to be in a condition for allowance. Applicants respectfully request early allowance of the application. Applicants also request that the Examiner contact the undersigned, if it will assist further examination of this application.

Applicants believe that a three month extension of time is required, and hereby request that the associated fees be charged to Deposit Account No. 19-4972. Applicants also request that any other fee required for timely consideration of this application be charged to Deposit Account No. 19-4972.

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Respectfully submitted,

/Kathryn E. Noll, #48,811/
Kathryn E. Noll
Reg. No. 48,811
Attorney for Applicants

Sunstein Kann Murphy & Timbers LLP
125 Summer Street
Boston, MA 02110-1618
617-443-9292